

U.S. Patent Appln. S.N. 10/069,145
AMENDMENT

PATENT

REMARKS

This Amendment cancels claim 14, and rewrites claims 8-10, 12 and 15. The alkylsubstituted alkoxy silane feature of claims 8 and 12 is supported by claims 9 and 14, respectively. Claim 8 has been further amended by changing "comprising" to --consisting essentially of--. Claims 9, 10 and 15 have been amended to reflect the changes to claim 8. Claims 8-13, 15 and 16 are pending.

The 35 U.S.C. § 103(a) rejection of claims 8-16 over U.S. Patent No. 5,858,280 to Zhang et al. in view of U.S. Patent No. 5,804,318 to Pinchuk et al. is respectfully traversed. The claimed invention is a biodegradable silica xerogel composition comprising a silica xerogel which is capable of controlled release of a biologically active agent, and its method of preparation.

Page 3, first paragraph of the Official Action, argues that Zhang et al. discloses a biologically active agent. The Patent Office is respectfully requested to cite the column and line number where such disclosure appears, or concede such disclosure is absent from Zhang et al..

The Official Action also argues that Zhang et al. teaches that gels formed from compositions comprising tetraaethoxysilane and an alkyl substituted alkoxy silane are suitable carriers for biologically active agents. Again, the Patent Office is

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respectfully requested to cite, by column and line number, where such disclosure can be found, or concede such disclosure is absent from Zhang et al..

The cited combination of references fails to raise a *prima facie* case of obviousness against the claimed composition and method. Zhang et al. fails to disclose or suggest a biodegradable silica xerogel composition which can be used for the controlled release of a biologically active agent. Instead, Zhang et al. teaches a transparent silica gel, useful as a host material for doping optically functional molecules. There is no indication that the Zhang et al. transparent silica gel is biodegradable. In this regard, one of ordinary skill would know that residual silanol groups in the xerogel composition are responsible for biodegradability. Zhang et al. teaches an optional heat treatment which will eliminate such residual silanol groups (Col. 5, lines 3-21). Accordingly, one of ordinary skill in the art, seeking a xerogel composition for controllably releasing a biologically active agent such as heparin, is given no disclosure or suggestion that the Zhang et al. composition is biodegradable or that it is suitable for the controlled release of a biologically active agent such as heparin.

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Pinchuk et al. also fails to disclose or suggest that an anti-thromogenic agent such as heparin can be encapsulated into sol-gel derived xerogel derived from tetraalkoxysilane which has been co-hydrolyzed with an alkylsubstituted alkoxy silane, or that heparin may be controllably released from the xerogel. Instead, Pinchuk et al. discloses a surface coating comprising a non-silica hydrogel containing pendant primary and tertiary amine groups (Col. 3, lines 26-29).

Pinchuk et al. is cited to show an epoxy-functionalized silane primed catheter dipped into a hydrogel solution containing 2% heparin. However, the silane coupling agent is used only for silylation of the surface of the material to be coated. The coating itself is not made of sol-gel derived silica xerogel derived from tetraalkoxysilane. Pinchuk et al. expressly teaches that the anticoagulant agent is bound to quaternary ammonium cations present in its (non-silica) hydrogel. See Col. 3, lines 31-33, Col. 5, lines 13-15 and Fig. 4. There is no teaching or suggestion that heparin may be controllably released from a sol-gel derived silica xerogel derived from tetraalkoxysilane.

One of ordinary skill in the art, seeking a biodegradable silica xerogel composition which is capable of controlled release of heparin, would not be led to the claimed composition and method

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by Zhang et al. and Pinchuk et al. Reconsideration and withdrawal of the obviousness rejection of claims 8-16 over Zhang et al. in view of Pinchuk et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 8-11 over Kuncova et al., 60 Collect.Czech.Chem.Commun. 1573 (1995) in view of Pinchuk et al. is respectfully traversed. The inventors have discovered a biodegradable composition comprising a silica xerogel which is capable of controlled release of a biologically active agent. A feature of the claimed biodegradable composition is the partial replacement of a tetraalkoxysilane with an alkylsubstituted alkoxy silane.

The combination of Kuncova et al. and Pinchuk et al. fails to raise a *prima facie* case of obviousness against the claimed composition. More particularly, Kuncova et al. fails to disclose the partial replacement of a tetraalkoxysilane with an alkylsubstituted alkoxy silane. Pinchuk et al. merely discloses a non-silica hydrogel bound to a surface to be coated by a silane coupling agent.

Reconsideration and withdrawal of the obviousness rejection of claims 8-11 over Kuncova et al. in view of Pinchuk et al. is respectfully requested.

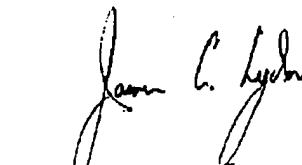
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It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 8-16, and issuance of a Notice of Allowance directed to claims 8-13, 15 and 16, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

It is not believed any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge our Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,



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